MAY - 5 2004

510(k) Summary

K040196

Kendall ePump™ Enteral Feeding Pump and Enteral Feeding Sets

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Tyco Healthcare/Kendall
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: January 28, 2003

1. Contact Person

Bridget Gardner
Manager, Regulatory Affairs
(508)-261-6384

2. Name of Medical Device

Classification Name: Infusion Pump

Common or Usual Name: Enteral Feeding Pump

Trade Name: Kendall ePump™ Enteral Feeding Pump and Enteral Feeding Sets

3. Identification of Legally Marketed Device

The proposed Kendall ePump™ Enteral Feeding Pump and Enteral Feeding Sets is substantially equivalent in intended use, function and mode of operation to the currently marketed Kangaroo® 524 Enteral Feeding Pump & Administration Sets (K945964).

4. Device Description

The ePump™ platform is a new enteral feeding system comprised of an enteral feeding pump and disposable Enteral Feeding Sets. This Class II device is an enteral feeding pump that delivers formula via rotary peristaltic tension loop pumping to provide nutrition for those who do not have the ability to orally ingest food. This enteral feeding pump is an attitude independent pump offering a streamlined graphical user interface that walks the user through the ePump™ setup and operation with many new features to allow the ability to both feed nutrition and flush when required.

The ePump™ Enteral Feeding Pump Sets are compatible with standard prefilled formula containers presently available on the market. The ePump™ enteral feeding pump sets are also designed to be compatible with present marketed enteral access devices and accessories (extension sets).

5. Device Intended Use

Intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding, pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging

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from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to a patients gastrointestinal system.

6. Product Comparison

The Kendall ePump™ Enteral Feeding Pump and Enteral Feeding Sets are substantially equivalent in intended use, function and mode of operation to the currently marketed Kangaroo® 524 Enteral Feeding Pump & Administration Sets (K945964).

7. Nonclinical Testing

Biocompatibility testing of the proposed device has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Ms. Bridget Gardner
Manager, Regulatory Affairs
Tyco Healthcare/Kendall
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K040196
Trade/Device Name: Kangaroo® ePump™ Enteral Feeding Pump and Enteral Feeding Sets
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZH
Dated: April 27, 2004
Received: April 28, 2004

Dear Ms. Gardner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040196

Device Name: Kangaroo® ePump™ Enteral Feeding Pump and Enteral Feeding Sets

Indications For Use:

Intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding, pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to a patients gastrointestinal system.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040196

Prescription Use _√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)